



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/814,749	03/30/2004	Dominique Charmot	29329-715.201	7226

56631 7590 03/23/2006

WILSON SONSINI GOODRICH AND ROSATI / ILYPSA, INC.
650 PAGE MILL ROAD
PALO ALTO, CA 94304

EXAMINER

YOUNG, MICAH PAUL

ART UNIT PAPER NUMBER

1618

DATE MAILED: 03/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/814,749	Applicant(s) CHARMOT ET AL.	
	Examiner Micah-Paul Young	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3,4,14,15,18-22,29,30,34,36,40 and 51-63 is/are pending in the application.
- 4a) Of the above claim(s) 34,36,40 and 51-63 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3,4,14,15,18-22,29 and 30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgment of Papers Received: Response/Amendment dated 11/22/05.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 3,4,14,15,18-22,29,30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. As discussed above potassium-binding polymers are not mentioned in the specification by name or exemplified by the examples. Potassium-binding polymers are never mentioned in the specification and are not exemplified in the examples. Only phosphate-binding polymers are described by the specification. Applicant has not provided sufficient disclosure to distinguish potassium-binding polymers from phosphate or any other ion binding polymers. These new amendments represent new matter.

Election/Restrictions

3. Newly submitted claims 51-63 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the claims were not presented in the original restriction requirement and represent a new and distinct invention.

Art Unit: 1618

4. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 51-63 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

5. Claims 34,36 and 40 are withdrawn from consideration as not directed to the elected pharmaceutical dosage form of group I.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 3,4,14,14,18-22,29, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Tyler et al (US 2004/0166156) and Bandi (USPN 4,902,501).

Art Unit: 1618

9. Tyler discloses a particle (tablet) comprising a core and a shell material (coating), see abstract. The particles target a solute as claimed, as they are for lowering serum phosphate levels in patients by removing the phosphate from the gastrointestinal tract, see page 1. The core includes the same polymers as recited in the specification as useful in the invention, e.g. polyallylamine, etc., which may be crosslinked with the same crosslinking agent as recited by applicant, e.g. epichlorohydrin, etc., see pg. 1-2 and pg. 2 [0019]. The cores include a non-metal material. The coating or shell material includes various polymers, including cellulose, etc. see page 2 [0013]. The coating would be physically attached to the core, as it is coated thereon. The particles would inherently be expected to satisfy the functional limitations set forth in the claims, since the particles contain the same components, i.e. the same core polymers and are used for the same purpose. A compound and its properties cannot be separated. The particles are used for therapeutic methods, including removing toxins, by lower phosphates (to treat renal failure) and lowering cholesterol see page 1. Though the reference is silent to the specific removal of potassium ions, it is the position of the Examiner that these polymers would inherently possess these properties. The polymers recited by Tyler are relied upon for the purposes of the instant invention throughout the specification, and though not expressly recited, it remains the position of the Examiner that the polyallylamine polymers of Tyler would also bind potassium. The reference is silent to the specific thicknesses recited by applicant.

10. Bandi teaches particle for the same use of Tyler and teaches that the particles may have a size of 5 microns, of 500 um; see column 2.

11. It would have been obvious to optimize the size of the particles disclosed by Tyler and to be within the claimed ranges because it is known in the art particles size and shell thickness

Art Unit: 1618

may be optimized to include the ranges as claimed to optimize various properties of the particles (disintegration times, amount of polymer, etc.) as shown by Bandi.

Double Patenting

12. Claims 3,4,14,15, and 18-22 of this application conflict with claims 1,10,16,17,20-24 of Application No. 10/813,872. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

13. Claims 3,4,14,15, and 18-22 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1,10,16,17,20-24 of copending Application No. 10/813,872. Although the conflicting claims are not identical, they are not patentably distinct from each other because both set of claims recite pharmaceutical formulations comprising core-shell formulation comprising potassium-binding polymers that are crosslinked. The formulations both have shells with thicknesses up to 50 microns. These claims would act as obviating art over each other.

14. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Correspondence

Art Unit: 1618

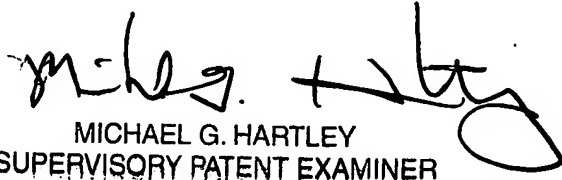
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608. The examiner can normally be reached on M-F 7:00-4:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Micah-Paul Young
Examiner
Art Unit 1618

MP Young


MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER